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Mr Guinness CA-OPU

Ref: Guinn62

From: Dr A Rejman CA-OPU2

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Copy: Mr Pudlo CA-OPU2

DRAFT SUBMISSION - BPL

1. Thank you for sending me your draft submission. I would like to first of all make comments on the submission as it is, and then get back to you at a later date with the specific sections that Paul and I need to prepare.
2. Para 4 - I wonder whether it would be worthwhile asking the NBA to produce a table, an expanded version of Appendix 1, since the various figures for tons of plasma used for individual products is confusing and if one adds up all the figures they are greater than the 580 tons. This is because different fractions of the same plasma are used for different products. I would suggest therefore that they should outline the different fractions that are obtained from plasma, the Factor VIII part, the immunoglobulin part and the Albumin part, so that PS(H) can see what comes out of a kilogram of plasma. They could then prepare a table say for the years 1990-1995 with the following headings, figures in tons and under each item it would be worthwhile stating profit/loss in millions of pounds for each year:

Ordinary plasma supplied to BPL by the BTS and cost; Factor VIII production from this blood, sold in UK, sold abroad; Factor IX produced, sold in UK, sold abroad; Albumin produced, sold in UK, sold abroad; ordinary ImIg produced, sold in UK, sold abroad; IvIg produced, sold in UK, sold abroad; untreated plasma, sold, destroyed, put in store; intermediates, sold, destroyed, put in store.

Although I accept that this is commercially sensitive information, I think this information must be made available to PS(H) to allow him to make a sensible decision.

3. My understanding is that the price for plasma was guessed at, and did not relate to world prices or to the actual value to BPL. It may well have been designed to keep the price of red cells as low as possible.
4. I wonder whether if it is worth putting in an additional paragraph after para 4, something like the following:

Some special immunoglobulins are produced from special donors, such as for Anti-D, rabies etc. This is paid for separately and at a marked premium because it costs a lot more to collect.

5. End of para 5 - suggest add the following:

".... over-capacity in the UK. There is also over-capacity in the non-profit sector in western Europe generally."

6. Para 6, towards the end of line 4 - suggest add the word "allow" before the word "use" and then add the word "of".

7. Para 8, first bullet point, 2nd sentence - this needs correction. Higher purity Factor VIII uses more plasma. Suggest change the 2nd sentence to the following:

"With greater use of red cells rather than whole blood for transfusion we are now approaching the situation market. This is despite viral inactivation and the development of higher purity Factor VIII, both of which have led to less Factor VIII being recovered from the plasma".

8. Para 8, 2nd bullet point - because over the years there has been such variation in the Factor VIII use and BPL's share, I wonder whether you would like to consider again whether it is worth appending the graph from the Haemophilia Directors.

9. Para 10, end of the 3rd sentence - suggest add the following:

"although the known viruses are thought to be of little importance for most patients."

10. Para 10, market penetration of recombinant Factor VIII. We still have little information on which to base our predictions. On looking at the Bain review in 1993, they predicted 2.6% recombinant Factor VIII out of a market of approximately 160 million units in 1995. We believe that the actual proportion was probably 10%. BPL are now predicting 30% at the end of 96/97. They have no evidence for this prediction, and they have not taken into account the effect of the VAT imposition. I understand that the Haemophilia Directors will be preparing a guidelines document on management of haemophilia later this year. There is no consensus among the haemophilia treaters as to what is the best treatment. I think that all that we can tell Minister is that the future is uncertain and will be determined by 2 factors, the relative price of recombinant Factor VIII v plasma derived Factor VIII, and any major episode of infection in the UK (or abroad) using plasma derived Factor VIII.

11. Para 11 - I do not believe there is a recombinant Albumin. I would therefore suggest changing the first sentence to the following:

Albumin has never been known to transmit infection and it is used as a carrier for recombinant Factor VIII, so even this has a theoretic risk.

12. End of para 11 - I wonder whether it is worth pointing out that these small volume "orphan" products could be produced by arrangement with PFC or other European non-profit manufacturers.

1. Your table giving the various options, unfortunately will need a health warning. This is that as recombinant Factor VIII starts taking market share, then plasma will have to be destroyed whatever option is chosen. Also as plasma derived Factor VIII will no longer bring in much income, then the cost of red cells and/or the cost of other plasma derived products will have to rise to cover the short fall in income.
14. I am not convinced that partnership with other not for profit fractionators is a realistic option.
15. Para 15(d) - I am not sure where this suggestion has come from. It is unrealistic, since it would require a much increased nursing and medical cover at transfusion centres. It will also take much longer to take a unit, at least twice as long. It would also involve the use of much more complicated equipment and specialised bags.
16. Appendix 2, para 1, subpara 3 - BPL has already been accused of unfair competition from BPL's competitors. A case has gone forward to OFT on predatory pricing in respect of high purity Factor VIII. We have tried to head this off, but I am not sure whether the case has finally ended. It would be worthwhile putting in the latest situation in this Appendix.
17. Appendix 2, para 4, line 3 - suggest change to the following:
"Some doctors have shown a loyalty to the NHS"
18. Appendix 2, para 5 - I think we must tell PS(H) that the issue of burning plasma is essentially a ploy by the NBA to try to blackmail Ministers. Blood is wasted all the time due to incomplete donations, bags broken in transit, expiry of units, etc. No one makes a fuss of this, although they do try to minimise these events. Plasma overall is a by-product which has had its day. One would no more think of saving all the urine specimens that are collected in hospital for testing because they happen to have come from humans. Ultimately, the only people that will complain about destruction of plasma will be the NBA themselves. However, we must try to do what we can to prevent them mounting a media campaign trying to highlight this.
19. Appendix 2, para 6, subpara 2, line 2 - suggest add the words "on grounds of public health" after the words "France bans imports".
20. Appendix 2, para 7 - suggest adding the following at the end of the 2nd sentence:
" , but there is now little difference in safety between imported paid plasma derived blood products and those from unpaid donors, since both are subject to the same tests and viral inactivation procedures".

2. Appendix 2, para 9 - I mentioned earlier that I think the suggestion of co-operation with other non-profit fractionators is doomed to failure. Admittedly we might be able to convince Ministers to agree with their Scottish colleagues some form of rationalisation between PFC and BPL, but this would mean that some of the work at least would have to stay at PFC. It is highly unlikely that other countries would give up their current work, and Governments would protect this, particularly if this led to unemployment.

22. Appendix 3, para 4 - suggest changing the first sentence to the following:

"By making plasma-based productsextending the useful life of BPL although ultimately it is unlikely that a solution to the plasma surplus would be found."

23. Appendix 3, para 5, first sentence - suggest amend to the following:

"Some European countries derived from paid donors, as the commercial companies overall have a past record of good supply, whereas BPL has only just reached a situation of excess plasma, and purchasers may be anxious that this situation may not be sustained. Self-sufficiency is considered a national rather than a EU concept (despite the Commission's entreaties) and so countries do not feel any particular need to buy plasma or products from unpaid donors. Also they prefer not to buy BPL products because BTS blood is not ALT tested."

24. Appendix 3, para 5 - suggest adding the following sentence before the final one:

"There might in future be other tests not based on safety that would need to be introduced if BPL were to retain these markers."

25. Appendix 3, para 5, last sentence - suggest adding at the end of the final sentence the following:

", although whether UK should subsidise this is questionable."

26. Appendix 3, para 6 - suggest adding after the 2nd sentence the following:

"Unfortunately, currently there is an excess capacity for fractionation of such plasma and some fractionators, eg in France, have already closed."

27. Appendix 3, para 7 - I have earlier referred to my doubt about this possibility.

28. Appendix 3, para 8 - suggest adding after the 2nd sentence the following:

"This could be interpreted as sale of plasma for commercial gain, albeit ultimately for BPL and the NHS, although it would not be represented as such by the media."

29. Appendix 3, para 8, 3rd sentence - suggest amend to the following:

"Commercial partners previously considered all insisted on ALT testing, ..."

30. Appendix 3, para 8, end of the 4th sentence - suggest add the following:

"and some of BPL's products might need to be sacrificed. Tight agreements would need to be made to avoid the commercial partner and BPL competing in the UK."

31. Other point that might be worth making somewhere in the submission, although I am not sure where this would be best placed, is the concept that BTS and BPL should cover their own costs. We have in the recent past had two episodes where failures on the part of the transfusion service have been paid for by BPL and ultimately DH. These were as follows. At the time when the CPMP insisted that all blood products should be made from hepatitis C tested plasma, North London BTC had a substantial amount of plasma which had not been tested. They insisted that BPL bought this plasma from them, which BPL agreed to do, and this was ultimately destroyed. In a later incident, plasma from North London BTC and Manchester BTC was contaminated with hepatitis C. BPL asked DH to pay for the withdrawal of the blood products involved. In this case DH made a special payment to BPL to cover the cost of these products. In both cases it would have been appropriate for the BTS that was at fault, to cover the costs of its failings.
32. Happy to discuss.

GRO-C

Dr A Rejman

Room 420 Ext

EH

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